INDIVIRTUS

INDIVIRTUS HEALTHCARE SERVICES PVT. LTD.

Celebrating in just 3 years

- 3500+ PDE Reports
- 30+ International Clients
- 160+ Domestic Clients

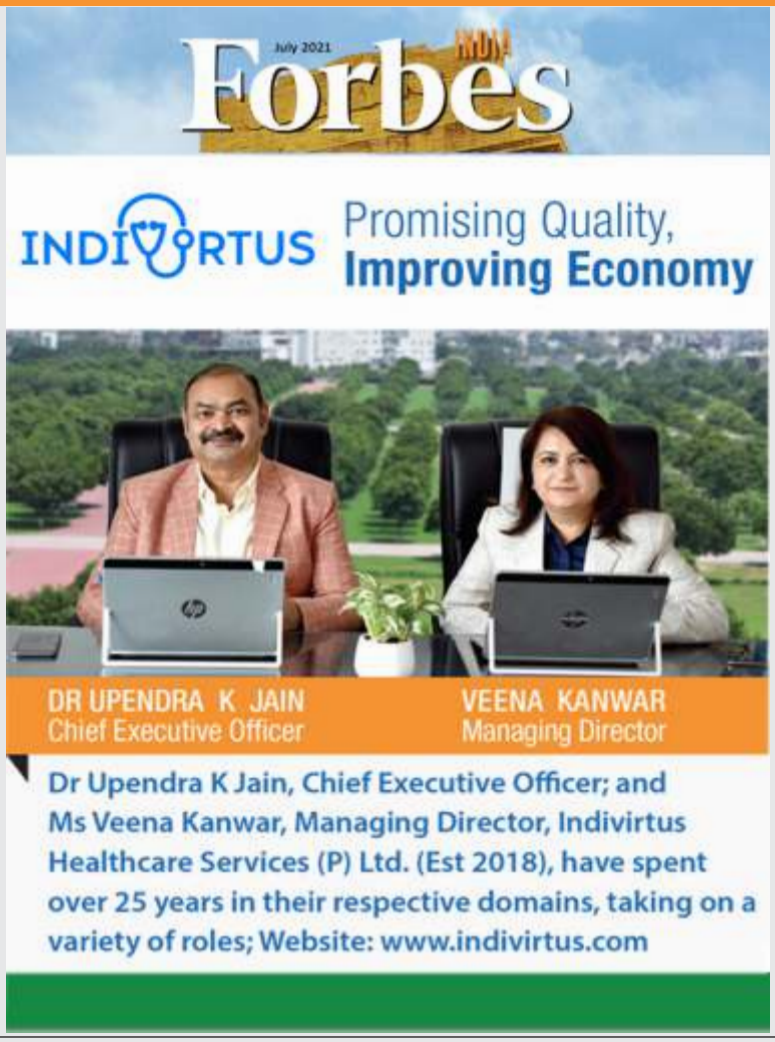
ABOUT US

Indivirtus (Indian company with virtuousness, character, courage, transparency & truthfulness having its base in Chandigarh, India) is a CRO which offers cost effective solutions without compromising on quality.

OUR USP

Unique
Selling
Proposition

- Only company with a team of 6 Certified Toxicologists
- Average output of 40 PDE/ADE & OEL reports per week in EMA format
- Experience of preparing 3500+ PDE/ADE & OEL reports and 350+ Genotox Evaluation Report of impurities
- Served 30+ International and 160+ Domestic Clients in just 3 years
- End to End Pharmacovigilance services headed by a professional with 30+ years of global experience
- Clinical Trials headed by a professional with 29+ years of experience
- GxP services headed by a professional with 27+ years of experience
- Experience of developing 100+ sterile and non-Sterile formulations in DSIR approved lab
- GLP and NABL approved animal toxicity lab
- USFDA, MHRA, PICS, GCC and WHO approved BA BE facility

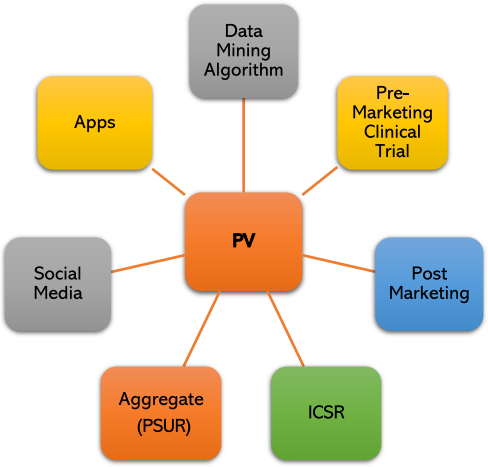


Benefits of outsourcing to Indivirtus	
Helps optimize your resources	Reduced costs of operations
Cost-effective services	Reduced cost of hiring and training

PHARMACOVIGILANCE

For Drug Safety and Expedite Approvals

- Pharmacovigilance System Set-up
- PSMF Management
- SOPs and SDEA Management
- Handling of Medical Queries through Medical Information Call Centre
- Adverse Event and Product Complaint Management
- ICSR Case Processing and Reporting
- Safety Narrative Writing
- Literature Surveillance
- Aggregate Report Management
- Risk Management Plan
- Signal Management
- Audits and CAPA Management



TOXICOLOGICAL RISK ASSESSMENT

- Genotoxicity and Mutagenicity Evaluation of Impurities using Derek & Sarah Software/ Toxtree, as per ICH M7 Guidelines
- PDE/ADE & OEL Calculation for APIs and Formulations
- QSAR Analysis
- HACCP (Hazard Analysis Critical Control Point)

ICH M7 | Derek nexus | Sarah nexus

BA/BE STUDIES

(USFDA/MHRA/EU/PICS/GCC approved facility)

- BA-BE Studies (For small and larger molecules)
- Bio Analytical Services
- Analytical Services
- Analytical Method Development & Validation
- Extractable & Leachable Testing for Injectable
- Elemental Impurities Testing
- Nitrosamine Testing

24 X 7 Medical Information Call Centre

GxP

Medical Writing

Clinical Trial Management

Global Market Research

Formulation Development & Tech Transfer

Pharmacovigilance

Toxicological Risk Assessment

Regulatory

Clinical Writing

Bioequivalence Study

Animal Studies

Analytical Services including Extractable Leachable Testing

GxP & REGULATORY

- GAP assessment audits / Due Diligence Audits
- Vendor Assessment Audits
- Reduction of Operational Redundancies in Manufacturing & Quality Control
- Production Process Integration, Process Optimization & Yield Improvement
- CAPA, OOS and risk management with appropriate mitigation and contingency plan
- Managing Regulatory response & Remediation activities (USFDA & EU)
- Implementation and monitoring of Quality Systems compliance based on FDA's six quality systems approach
- Equipment Qualification and Validation
- Process controls and Validations
- PLC Validation
- CSV Validation
- People development through training and demonstration
- Health Hazard Evaluation

MEDICAL WRITING

Regulatory Writing

- New Product Authorization- IND, NDA, ANDA
- Post Approval Changes and Product Lifecycle Management
- Clinical and Non-Clinical Overviews
- Clinical Expert Statements
- Bio waiver Expertise
- eCTD/CTD dossier compilation

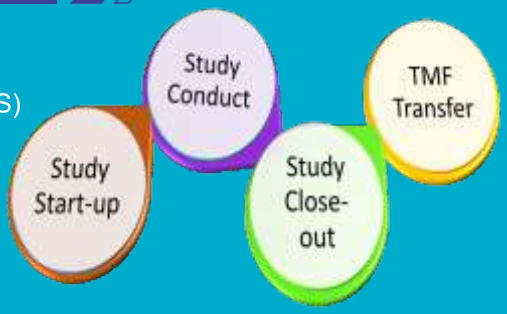
Clinical Writing

- Investigator Brochures
- Clinical Study Protocols
- Clinical Study Reports (CSRs)
- Informed Consent Documents
- Patient Safety Narratives
- Clinical Evaluation Reports (CER) for Medical Devices

INDIVIRTUS HEALTHCARE SERVICES PVT. LTD.

CLINICAL TRIAL MANAGEMENT

(For small and larger molecules)
- Phase I-IV Clinical Trials
- Active Post Marketing Surveillance (APMS or PMS)
- Data Procurement Management
- Patient Recruitment and Retention
- Study Monitoring
- Medical Writing & Reporting
- Pharmacokinetics / Pharmacodynamics (PK/PD)
- Medical Monitoring



GLOBAL MARKET RESEARCH

- Health Economics and Outcome Research
- Consumer research
- Online panel research
- Quantitative data collection
- Qualitative fieldwork research
- Market research reports
- Market sizing & forecasting
- Competitive landscape analysis
- Indication-wise pipeline analysis

ANIMAL STUDIES

BIOPHARMA/BIOTECH/STEM CELL
- Acute toxicity Studies (Single Dose)
- Sub-acute toxicity Studies (14/28 days)
- Sub Chronic Toxicity Studies (90 days)
- Chronic Toxicity Studies
- Genetic Toxicity Studies
- Repeated Dose Toxicity Studies
- Repeat Dose Inhalation Studies
- Developmental & Reproductive Toxicology
- Immunotoxicity Studies
- Reproductive Toxicity Studies

MEDICAL DEVICES
(Leachable/ Extractable and Material Testing)
- Biocompatibility studies
- Genotoxicity Test
- Implantation Studies
- Cytotoxicity and Hemocompatibility Studies
- Skin Sensitization
- Irritation and Hypersensitivity Studies
- Systemic Toxicity
- Immunotoxicity Studies

INDIVIRTUS HEALTHCARE SERVICES PVT. LTD.

24 X 7 Medical Information Call Centre

GxP

Medical Writing

Clinical Trial Management

Global Market Research

Formulation Development & Tech Transfer

Pharmacovigilance

Toxicological Risk Assessment

Regulatory

Clinical Writing

Bioequivalence Study

Animal Studies

Analytical Services including Extractable Leachable Testing

FORMULATION DEVELOPMENT

- Technology Transfer
- Biosimilar
- Diagnostic Antigen
- API by Fermentation Technology
- ICH Stability and Photostability study
- Molecular Reagents & Antibodies

Product ready for Tech -transfer

Code	Product	RLD Name	Strength and Dosage Form
IHS2	Omega 3 fatty acid **(PATENTED)**	Lovaza® (Woodward Pharma)	880 mg Soft Gel Capsule
IHS1	Bisacodyl	Dulcolax DR Tablets	5 mg EC Tablet
IHS1	Chlorpromazine HCl	USL	10, 25, 50, 100, 200 mg Tablet
IHS2	Deferasirox	Exjade (Novartis)	125, 250 and 500 mg Tab for oral suspension
IHS2	Deferasirox	JADENU (Novartis)	90, 180, 360 mg Film coated Tablet
IHS2	Deferasirox	Jadenu® Sprinkle (Novartis)	90, 180, 360 mg Sprinkle
IHS1	Dexamethasone Acetate	Dectanyl	0.5, 0.75 mg Tablet
IHS2	Disulfiram	Antabuse® (Teva)	200 mg IR Tablet
IHS2	Doxylamine/Pyridoxine DR	Diclegis® (Duchesnay)	10, 10 mg DR tablets
IHS2	Doxylamine/Pyridoxine ER	Bonjesta® (Duchesnay)	20, 20 mg ER tablets
IHS2	Ezetimibe	ZETIA 10 mg (MSD INTL GMBH)	10 mg IR Tablet
IHS1	Famotidine	Gaster	10, 20 mg Tablet
IHS1	Famotidine	NA	40 mg / 5 ml Suspension
IHS2	Glipizide	GLUCOTROL XL (PFIZER)	2.5, 5, & 10 mg ER Tablet
IHS1	Hydroxychloroquine Sulphate	Plaquenil	200 mg Tablet
IHS2	Ibuprofen (EU)	Brufen Retard (FAMAR SA)	800 mg SR Tablets
IHS1	Ibuprofen Famotidine	Duexis	800+26.6 mg Tablet
IHS1	Linezolid	Zyvox	600 mg Tablet
IHS1	Melatonin	Circardin	2 mg Prolong Tablet
IHS1	Mesalamine	Pentasa Sachets	90,96% ER Pellets
IHS1	Metformin	Glumetza	500, 1000 mg ER Tablet
IHS2	Niacin	NIASPAN (ABBVIE)	500 , 750; 1000 mg ER Tablet
IHS1	Nimodipine	Nimotop	30 Tablet
IHS1	Olmesartan + HCTZ	Benicar HCT	20 + 12.5, 40 + 12.5, 40 + 25 mg Tablet
IHS2	Oxybutynin	DITROPAN XL (JANSENN PHARMA)	5, 10, 15 mg ER Tablet
IHS2	Paliperidone	Invega® (Janssen)	1.5,3,6,9 mg ER Tablets
IHS1	Posaconazole	Noxafil	100 mg DR Tablet
IHS2	Posaconazole	Noxafil (Merck)	100 mg DR Tablet
IHS1	Pregabalin	Lyrica	25, 50, 75, 100, 150, 200, 225, 300 mg Capsules
IHS2	Pregabalin	LYRICA (Pfizer)	25,50,75,100,150, 200, 225 & 300 mg IR Capsule

Products under Development

Code	Product	RLD Name	Strength and Dosage Form	Remark
IHS1	Sugammadex	Bradion	100 mg / ml (2m and 5 ml) Injection	under filing
IHS1	Abiraterone Acetate	Zytiga	500 mg Tablet	Poilt Ongoing
IHS2	Acyclovir; Hydrocortisone	Xerese®	5%; 1% w/w Cream	API source evaluation is under progress.
IHS2	Aminocaproic acid	Amicar® (Akorn)	1.25 g/ 5mL Oral Solution	Literature survey completed
IHS2	Amlodipine and Celecoxib	Consensi® (Coeptis)	2.5/200; 5/200; 10/200 mg IR tablet	Stability initiated
IHS2	Aprepitant	Emend® (MERCK)	40, 80 & 125 IR Capsule	Awaiting to schedule pilot bio
IHS1	Artemether + Lumefantine	Riamet	20+120, 80+ 480 mg Tablet	Development Ongoing
IHS2	Ashwagandha & Others	N/A	1% w/w Gel	Prototype Ready
IHS1	Atorvastatin Calcium Trihydarte	Lipitor	10, 20, 40 mg Tablet	Devlopment done
IHS2	Bortezomib	Velcade	3.5mg/vial Injection	Source identified. Non-infringing formula trials at FD under Progress.
IHS2	Brimonidine	Mirvaso® (Galderma)	0.33% w/w Gel	API source identified and under evaluation.
IHS2	Cardamon & Clove	N/A	5 / 5 mg Chewable Tablet	Prototype Ready
IHS2	Clindamycin Phosphate Benzoyl peroxide	Acanya® (Bausch)	1.2% / 2.5% w/w Gel	API source finalised and prototype formulation stability initiated
IHS2	Crotamiton	Eurax®	10% w/w Lotion	API source evaluation is under progress.
IHS2	Curcumin	N/A	10 mg Orally soluble Tablet	Pilot bio is completed. Ready for TT
IHS2	Cyclophosphamide		200-400mg/ml Injection	Source identified. Non-infringing formula trials at FD under Progress.
IHS1	Cysteamine Bitartarate	Procysbi	25, 75 mg DR Capsule	Development Ongoing
IHS2	Dapsone	Aczone® (Allergan)	7.5% w/w Gel	API source finalised and prototype formulation stability initiated
IHS1	Dexamethasone	HEMADY	20 mg Tablet	Prototype Ready
IHS2	Dexlansoprazole	Dexilant® (Takeda)	30,60 mg DR capsule	API identified and prototype initiated
IHS2	Doxepin	Zonalon®	5% w/w Cream	Patent evaluation is under progress.
IHS2	Ephedrine Sulfate	AKOVAZ®	50 mg/ml – 1ml Injection	Raw material and pack material sourcing under progress
IHS2	Esmolol HCL	BREVIBLOC®	2GM/100ML & 1 GM/100ml Infusion bag (Injection)	Raw material and pack material sourcing under progress
IHS2	Esomeprazole	Nexium® (AstraZeneca)	20, 40 mg DR Capsule	Prototype is ready
IHS2	Famotidine and Ibuprofen	Duexis® (Horizon)	26.6/800 mg IR tablet	Stability under process
IHS2	Ferric citrate	Auryxia® (Kerry Bioscience)	210 mg IRON IR Tablet	API source selection under process
IHS1	Isosorbite Mononitrate	Imdur	60 mg SR Tablet	Pilot intiated
IHS2	Isosulfan Blue	LYMPHAZURIN® (Covidien Inc)	50 mg/5mL (10 mg/mL) Solution- Injection	Raw material and pack material source identified (DMF source). Development yet to start.
IHS2	Ivermectin	Soolantra® (Galderma)	1% w/w Cream	API source finalised and prototype formulation stability initiated
IHS2	Ketorolac Tromethamine USP	TORADOL®	15mg/ml-1ml & 30mg/ml- 1ml & 2 ml Injection	Raw material and pack material sourcing under progress
IHS2	Lacosamide	VIMPAT® (Ucb Inc)	200 mg/20 mL (10 mg/mL) Solution- Injection	Pilot bio is completed. Ready for TT
IHS2	Lidocaine; Tetracaine	Pliaglis®	7%; 7% w/w Cream	API source evaluation is under progress.
IHS2	Lisinopril	Qbrelis®	1mg / mL Oral Solution	Pilot bio is completed. Ready for TT
IHS1	Mesalamine	Pentasa Capsules	250, 500 mg ER Tablet	6 M Stability Done Ready for TT

Products under Development

IHS1	Mesalamine	Lialda	1200 mg DR Tablet	6 M Stability Done Ready for TT
IHS2	Metformin + Vildagliptin	Eucreas® (Novartis)	1000/50; 850/50 mg IR Tablets	API source finalised and Prototype initiated
IHS1	Metformin Extended Release + Dapagliflozin	XIGDUO XR	2.5+1000, 5+500, 5+1000, 10+500, 10+1000 mg ER Tablet	
IHS2	Mirabegron	Myrbetriq® (Astellas)	25, 50 mg ER Tablet	Prototype is ready
IHS1	Nefidipine	Adalat GITS	30 mg ER Tablet	Development Ongoing
IHS2	Neostigmine methylsulfate USP	BLOXIVERZ®	0.5mg/ml-10ml & 1mg/ml-10ml Injection	Raw material and pack material sourcing under progress
IHS2	Nicardipine HCL	CARDENE®	2.5mg/ml-10ml Vial- injection	Raw material and pack material sourcing under progress
IHS2	Nitazoxanide	Alinia® (Romark)	500 mg IR tablet	Stability completed
IHS2	Norepinephrine Bitartrate USP	LEVOPHED®	1mg / mL - 4mL fill Injection	Raw material and pack material sourcing under progress
IHS2	Oxybutynin Chloride	-	5 mg/ 5 mL Oral Solution	Product Ready for tech transfer
IHS2	Oxybutynin Chloride	DITROPAN®	5 mg / 5 mL Oral Syrup	Product Ready for tech transfer
IHS2	Ozenoxacin	Xepi®	1% w/w Cream	API source evaluation and literature search under progress
IHS1	Paliperidone	Invega	1.5, 3.0, 6.0, 9.0 mg ER Tablet	6 M Stability Done Ready for TT
IHS2	Pantoprazole Sodium for	PROTONIX IV®	40mg/vial Lyophilized - Injection	Raw material and pack material sourcing under progress
IHS2	Paroxetine HCl	Paxil® CR (Apotex)	12.5, 25, 37.5 mg CR Tablet	Prototype is ready
IHS1	Posaconazole	Noxafil Powder Mix Kit	300 mg DR Tablet	
IHS2	Posaconazole	Noxafil®	40 mg/ml Oral Suspension	In-vitro dissolution matches with RLD. Stability study under progress. Tech transfer can be done with in 3 month
IHS2	Pregabalin	Lyrica®CR (Pfizer)	82.5, 165 & 330 mg CR Tablets	Awaiting to schedule pilot bio
IHS2	Prochlorperazine Edisylate USP	COMPAZINE®	5mg/ml – 2ml Injection	Raw material and pack material sourcing under progress
IHS1	Prochlorprrazine Maleate	Procomp	5, 10 mg Tablet	Poilt ongoing
IHS1	Propranolol Hydrochloride	INDERAL LA	60, 80, 120, 160 mg ER Capsule	6 M Stability Done Ready for TT
IHS2	Ramelteon	Rozerem® (Takeda)	8 mg IR Tablet	Patent review under process
IHS1	Rifapentine	PRIFTIN	150 mg Tablet	Development Ongoing
IHS2	Selexipag	Uptravi® (Actelion)	800,1000, 1200, 1400, and 1600 mcg IR Tablet	API source finalised and literature survey done
IHS2	Simvastatin+ Ezetimibe	Vytorin® (MERCK)	10/10, 10/20,10/40, 10/80 mg Uncoated Tablets	Awaiting to schedule pilot bio
IHS2	Succinylcholine Chloride USP	QUELICIN®	20mg/ml – 10ml Injection	Raw material and pack material sourcing under progress
IHS2	Sucroferric Oxyhydroxide	Velphoro® (Fresenius)	500 mg Tablets	Product Identified for Development
IHS2	Sulconazole Nitrate	Exelderm®	1% w/w Cream	API source evaluation is under progress.
IHS2	Tacrolimus concentrated for solution for infusion	Prograf® (Astellas Inc)	5 mg/mL Injection	Initial and 3 M ACC completed Ready fot TT
IHS2	Valsartan and Sacubitril	Entresto® (Novartis)	24/26; 49/51; 97/103 mg IR Tablet	Stability initiated
IHS2	Vancomycin	-	5mg/ml Injection	Source identified. Non-infringing formula trials at FD under Progress.
IHS2	Verapamil HCL	ISOPTIN® (MT Adams)	2.5mg/ml – 2ml & 4ml Injection	2M ACC completed. Ready for TT
IHS2	Vigabatrin	Sabril® (Lundbeck)	500 mg Oral Solution	Prototype is ready
IHS2	Voriconazole	VFEND®	200mg/vial Lyophilized	Raw material and pack material sourcing under progress

GLOBAL FOOTPRINTS

INDIVIRTUS HEALTHCARE SERVICES PVT. LTD.
GLOBAL OFFICES

INDIA
1st Floor, D-258, Industrial Area,
Phase 8A, SAS Nagar,
Mohali, Punjab, India 160055
+91 9131925456 | +91 9425143905
+91 172 4028586 | director@indivirtus.com

UK
16 Bissley Drive,
Maidenhead, Berkshire
SL6 3UZ
+44 20 3286 0405
support.uk@indivirtus.com

USA
1100 Town & Country Road
Suite1250, Orange
CA 92868
+1 (323) 522-5967
support.usa@indivirtus.com

CANADA
Unit 307, 14255 Boul Gouin O,
Pierrefonds, Montreal
Quebec H8Z3C2
+1 639 318 7360
support.ca@indivirtus.com

Benefits of outsourcing to Indivirtus	
Delight for customers	Provides value added services
Improved business outcomes	Enhanced productivity